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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/218,481	12/22/98	VAN BRUGGEN	N 11669.41US01

HM22/0309

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EXAMINER

LINGAR, S

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/218,481

Applicant(s)

Van Bruggen et al

Examiner

Ungar

Group Art Unit

1642



☒ Responsive to communication(s) filed on Dec 12, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-6, 8-21, and 27-29 is/are pending in the application.

Of the above, claim(s) 3-6, 11-21, and 27-29 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 8-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The Amendment filed December 12, 2000 (Paper No. 13) in response to the Office Action of June 5, 2000 (Paper No. 10) is acknowledged and has been entered. Previously pending claims 2, 22 and 24-26 have been canceled, claims 1 and 8-10 have been amended Claims 1 and 8-10 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

4. Claim 8 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 10, Section 7, pages 4-5.

Applicant argues that the specification provides enabling disclosure for the claimed subject matter as amended since several types of variant antibodies including conjugates with cytotoxic moieties, fusions with non-immunoglobulin polypeptides and heterospecific antibodies, all of which can be made by recombinant methods are taught. The argument has been considered but has not been found persuasive because although the claim has been amended to recite a "chimeric murine antibody wherein at least one constant chain domain is replaced", the term "chimeric" is neither defined nor limited thereby. Further, neither the claim nor the specification teach which domain would be replaced, i.e. the Fc binding domain or the complement binding domain. Applicant's arguments have not been found persuasive and the rejection is maintained.

5. Claim 8 remains rejected under 35 USC 112, first second paragraph for the reasons previously set forth in Paper No. 10, Section 8, page 5.

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Applicant argues that amendment of the claim overcomes the rejection. The argument has been considered but has not been found persuasive because the amendment of the claim neither limits nor defines the term chimeric. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

6. Claims 1 and 8-10 remain rejected under 35 USC 102 for the reasons previously set forth in Paper No. 10, Section 10, pages 6-7.

Applicant argues that claim 1 has been amended to recite "determining the degree of cerebral edema" wherein the antibody reduces cerebral edema. Further, the claim as amended is directed specifically to reducing cerebral edema. The argument has been considered but has not been found persuasive because it is clear that the method, as previously disclosed, is inherently anticipated by WO94/10202 and that edema associated with glioblastoma is cerebral. Further, the prior art method exemplifies the *in vivo* inhibition of glioma associated tumor growth which inherently reduces (given the known nature of the tumor) cerebral edema and further inherently determines the degree of cerebral edema from the reduced tumor size since one would instantly envision the reduced cerebral edema from the reduced tumor size. Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claim 8 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitations of

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"at least one constant chain domain" in a step in the claimed method and the limitation of "a chimeric murine antibody" have no clear support in the specification and the claims as originally filed. Applicant points to support for the claim amendment on page 13, lines 6-10. A review of the specification discloses support for "substituting the coding sequence for selected human heavy and light chain domains" and "chimeric forms of murine antibodies". The suggested support is not found persuasive because there is nothing in the specification to suggest the specific limitation of replacement of at least one constant chain domain or a chimeric murine antibody. The subject matter claimed in claim 8 broadens the scope of the invention as originally disclosed in the specification.

8. Claims 1 and 8-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8-10 are indefinite because claim 1 recites the phrase "determining the degree of cerebral edema". The claims are confusing because it is not clear when this determination is made. For example, is the determination made before the administering step, after the administering step, or both?

Claim 8 is indefinite in the recitation of the term "homologous". The term "homologous" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of homology and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. All other objections and rejections recited in Paper No. 10 are withdrawn.

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10. No claims allowed.

11. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

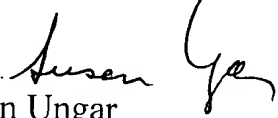
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.


Susan Ungar
Primary Patent Examiner
March 7, 2001